SAXENDA® REMS: Risk Evaluation and Mitigation Strategy

A REMS (Risk Evaluation and Mitigation Strategy) is a strategy required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product to ensure the benefits of a drug outweigh its risks.

The purpose of the SAXENDA REMS is to inform healthcare providers of the following serious risks associated with SAXENDA:

- **Potential Risk of Medullary Thyroid Carcinoma**
- **Risk of Acute Pancreatitis**

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Saxenda®
liraglutide (rDNA origin) injection

Potential Risk of Medullary Thyroid Carcinoma

BOXED WARNING: RISK OF THYROID C-CELL TUMORS

- Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice.
- It is unknown whether SAXENDA® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

Potential Risk of Medullary Thyroid Carcinoma (2)

Appropriate Patient Selection

- SAXENDA® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2).

Patient Management

- **Counsel patients** regarding the risk for MTC and inform them of symptoms of thyroid tumors (e.g., **mass in the neck, dysphagia, dyspnea, persistent hoarseness**).
- **Instruct patients** to contact their healthcare provider promptly if these symptoms occur.
- Patients with thyroid nodules noted on physical examination or neck imaging should be further evaluated.

Potential Risk of Medullary Thyroid Carcinoma (3)

Patient Management

- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value in patients treated with SAXENDA®. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated.

Risk of Acute Pancreatitis

- Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide.
- In clinical trials studying SAXENDA®, there were more cases of pancreatitis in patients treated with SAXENDA® than in patients treated with placebo.

Risk of Acute Pancreatitis (2)

Appropriate Patient Selection

- SAXENDA® has not been studied sufficiently in patients with a history of pancreatitis.

Patient Management

- After initiation of SAXENDA®, and after dose increases, **observe patients** carefully for signs and symptoms of pancreatitis.
- Counsel patients to contact their healthcare provider promptly if they experience symptoms of pancreatitis (including **persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting**).
- Discontinue promptly if pancreatitis is suspected.
- Do not restart if pancreatitis is confirmed.

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